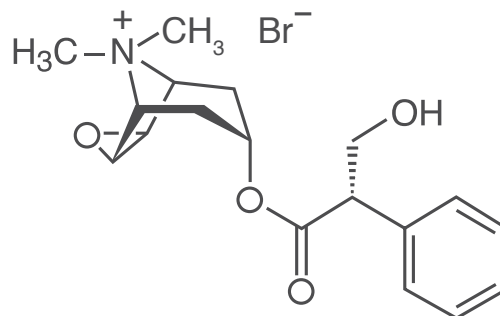


TECHNICAL DATA SHEET

METHSCOPOLAMINE BROMIDE USP

Formula : C₁₈H₂₄NO₄Br

CAS No	Mol. Weight	DMF Status
155-41-9	398.29	ACTIVE – Type II USDMF 7410 : Methscopolamine Bromide

ANALYSIS	SPECIFICATION	METHOD
DESCRIPTION:	White, crystalline powder, colourless.	Current USP monograph
IDENTIFICATION A:	I.R. spectrum corresponds to reference	Current USP monograph
IDENTIFICATION B:	Complies with bromide tests	Current USP monograph
OPTICAL ROTATION	-21 to -25 degrees	Current USP monograph
LOSS ON DRYING	NMT 2.0 %	Current USP monograph
RESIDUE ON IGNITION	NMT 0.1 %	Current USP monograph
RESIDUAL SOLVENTS: CLASS 2 (USP)	Complies with current USP requirements	Current USP monograph
RESIDUAL SOLVENTS: CLASS 3 (USP)	Complies with current USP requirements	Current USP monograph
ASSAY (USP):	97.0 % - 103.0 %	Current USP monograph
ORGANIC IMPURITIES:	Tropic Acid: NMT 0.1% Scopolamine Hydrobromide: NMT 0.1% Methylatropine bromide: NMT 0.1% Apomethscopolamine bromide: NMT 0.1% Any other impurity: NMT 0.1% Total impurities: NMT 0.5%	Current USP monograph

Products are manufactured according to the ICH GMP Guide for APIs

Products are manufactured under Phytex Australia GMP License (Australian Therapeutic Goods Administration (TGA))